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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/816,571	04/01/2004	B. Ron Johnson	15070.6.2	1232

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EXAMINER	
JAGOE, DONNA A	
ART UNIT	PAPER NUMBER
1614	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/816,571	JOHNSON, B. RON	
	Examiner	Art Unit	
	Donna Jagoe	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 May 2009 and 05 January 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *37-71* is/are pending in the application.

4a) Of the above claim(s) *48-52* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *37-47 and 53-71* is/are rejected.

7)☒ Claim(s) *56* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *1/12/09, 6/12/09 and 7/28/09*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of the group I invention, claims 37-47 and 53-71 in the reply filed on May 11, 2009 is acknowledged. The traversal is on the ground(s) that the elected invention is generic to the other species or subcombinations. This is not found persuasive because the subcombinations exclude oils or other tissue penetration inhibiting components (group II) and exclude menthol, thymol, eucalyptol, eugenol, camphor, hexetidine and anethol (group III) and thus the group I invention is not considered to be generic to the other species or subcombinations.

The requirement is still deemed proper and is therefore made FINAL.

Claims 48-52 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on May 11, 2009.

Claims 37-71 are pending in this application. Claims 48-52 are withdrawn.

Claims 37-47 and 53-71 are presented for examination.

Claim Objections

Claim 56 is objected to because of the following informalities: the word "comprisiung" in line 1 of the claim is misspelled. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 71 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

In particular, the portion of claim 71 drawn to "identifying disordered tissue caused by a virus (present in claim 71) is a concept that was not present in the specification as originally filed. Applicants are advised that the issue here is not whether particular instances of treatment of disordered tissue caused by viruses, bacteria or fungus are disclosed, but rather whether the concept of "identifying disordered tissue caused by a virus" was present in the specification as originally filed. The Examiner contends that a method of identifying disordered tissues caused by a virus was not present in the specification as originally filed.

Written Description

An applicant shows possession of the claimed invention by describing the claimed invention with all of its limitations using such descriptive means as words, structures, figures, diagrams and formula that fully set forth the claimed invention. *Lockwood v. American Airlines, Inc.*, 41 USPQ2d 1961, 1966 (Fed. Cir. 1997).

The Examiner is guided in his opinion that Applicant has not adequately described the presently claimed subject matter by the MPEP at § 2163 - 2163.05.

Considering the teachings provided in the specification as originally filed, the Examiner finds that Applicants have failed to provide the necessary teachings, by describing the claimed invention with all of its limitations using such descriptive means as words, structures, figures, diagrams and formula that fully set for the claimed invention, in such a way as to reasonably convey to one skilled in the relevant art that Applicants had possession of the concept "identifying disordered tissue caused by a virus".

Claim Rejections - 35 USC § 103

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 37-47 and 53-71 are rejected under 35 U.S.C. 103(a) as being unpatentable over Beauchamp et al. U.S. Patent No. 5,753,270 A and Remington's Pharmaceutical Sciences, 1975.

Beauchamp et al. teach a composition for treatment of skin afflicted diseases such as cold sores, fever blisters, Herpes Simplex II (genital herpes or non-oral skin of body (claim 70), (column 3, lines 10-13) and Herpes Simplex I (herpes labialis, aka herpes on the lips, mouth, or inside mouth) comprising applying to the skin an aqueous solvent system (column 3, lines 50-53) that comprises an antiseptic such as an alcohol and a quaternary ammonium antiseptic compound (column 4, lines 4-33). The alcohol can be isopropyl alcohol or the like, in water and the quaternary ammonium antiseptic compound may be benzalkonium chloride in an organic skin penetrating solvent (column 5, lines 25-35). Regarding the limitation of claim 37 drawn to penetration of the skin to form a reservoir of the treatment composition within the disordered tissue without rapidly diffusing beyond the disordered tissue, Beauchamp et al. teach immediately modifying the dried keratin layer of the epidermis for rapid penetration into the skin and for relief of pain, itching and destruction of viral and bacterial cells which are the source of the diseased skin condition (column 3, lines 28-34). It does not recite diffusion beyond the disordered tissue. Regarding the manner of application, it is generally understood that "apply liberally" would imply that the formulation is rubbed on the affected area (column 5, lines 56). The liquid is applied directly using a cotton swab or other type of applicator (finger) (see column 6). It would have been obvious to one having ordinary skill in the art at the time the invention was made to employ a towlette or a flat applicator to skin surface since the skin surface is flat and thus it would achieve the maximum contact with the skin. Regarding the limitation of claim 38 drawn to penetration of the skin or stratum corneum so as to form a reservoir of the treatment

composition within the stratum spinosum, Beauchamp et al. teach immediately modifying the dried keratin layer of the epidermis for rapid penetration into the skin and for relief of pain, itching and destruction of viral and bacterial cells which are the source of the diseased skin condition (column 3, lines 28-34). The claim elements appear in the prior art in the same configurations, serving the same functions, to achieve the results suggested in prior art, treatment of viral and bacterial disorders. Beauchamp et al. does not disclose the method wherein the carrier is 20-40% isopropyl alcohol or 70% isopropyl alcohol. Beauchamp however, discloses that the solvent is combined with water in an amount in the range exceeding about 50%. This amount overlaps with 70%. The recitation of the word "about" in instant claims 60-62 causes about 20% to about 40% (claim 60), about 60% to about 80% (claim 61) and about 70% (claim 62) isopropyl alcohol carrier to read on the prior art amount of about 50% (column 5, lines 25-26).

Beauchamp et al. does not disclose the method wherein the composition is no longer visible after about 2 minutes, however, all ingredients are water soluble in an aqueous solvent system. It is not expected that the medicament would be visible. Further, since isopropyl alcohol is a volatile substance, any remaining medicament that is not absorbed would volatize away, and not be visible. As noted in *In re Best* (195 USPQ 430 (CCPA 1977)), and *In re Fitzgerald(205* USPQ 594 (CCPA 1980)), the mere recitation of newly-discovered function or property, inherently possessed by things in prior art, does not cause claims drawn to those things to distinguish over prior art. In such a situation, the burden is shifted to the applicant to prove that subject matter shown to be in prior art does not possess characteristic relied on where it has reason to

believe that functional limitation asserted to be critical for establishing novelty in claimed subject matter may be inherent characteristic of prior art; whether rejection is based on "inherency" under 35 U.S.C. 102, on "prima facie obviousness" under 35 U.S.C. 103, jointly or alternatively, burden of proof is same. Regarding the limitation of claims 39-42 wherein the method of treatment is by application of the composition by rubbing, rubbing back and forth or compressing the disordered tissue, Remington's Pharmaceutical Sciences, 1975, recites that when the medicament is rubbed on vigorously, the amount of the preparation that is forced into the hair follicles and glands is increased (page 685, column 2, 2nd full paragraph). It would have been made obvious to one of ordinary skill in art at the time it was made to rub or compress the disordered tissue when applying the composition motivated by the teaching of Beauchamp et al. that the composition is topically applied and the teaching of Remington's Pharmaceutical Sciences that when the medicament is rubbed on vigorously, the amount of the preparation that is forced into the hair follicles and glands is increased (page 685, column 2, 2nd full paragraph).

Regarding the limitation of instant claim 64 drawn to the method wherein the disordered tissue comprises at least one lesion caused by herpes zoster virus, Beauchamp et al. teach treatment of herpes simplex (type I and type II). It does not teach treatment of herpes zoster virus. It would have been obvious to employ the quaternary ammonium halide compound and tissue penetrating agent of Beauchamp et al. for treatment of lesions caused by herpes zoster motivated by the teaching of Beauchamp et al. that viral and bacterial cells, which are the source of the diseased skin condition, are

destroyed (column 3, lines 28-34). Since Herpes Zoster is also a virus one of ordinary skill in the art would have employed the benzalkonium composition combined with a tissue penetrating agent, and the results would have been predictable.

Regarding claims 65 and 66 drawn to treatment of disordered tissue caused by smallpox virus and anthrax bacteria; Beauchamp et al. teach the destruction of viral and bacterial cells which are the source of the diseased skin condition by topical application to the skin (column 3, lines 3-34). The prior art showed destruction of viral and bacterial cells by topical application of the composition of an organohalide such as benzalkonium chloride and isopropyl alcohol in water. Therefore, it would have been obvious to one of ordinary skill in the art to substitute the smallpox viral cells or the anthrax bacterial cells the predictable result of the destruction of the viral and bacterial cells.

Thus the claims fail to patentably distinguish over the state of the art as represented by the cited references.

Accordingly, for the above reasons, the claims are deemed properly rejected and none are allowed.

Response to Arguments

In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., only a single application in the instant case is required to be effective) are not recited in the rejected claim(s). Although the claims are interpreted in light of the

specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

Applicant asserts that the method of the Remington's Pharmaceutical Sciences would penetrate through the skin and into the patients "circulation". In response, penetration into the hair follicles is not the same as penetration into the "circulation" or bloodstream. Hair follicles are oil glands. Further, applicant appears to be applying the same composition (quaternary ammonium chloride compound having 8-18 carbons combined with a skin penetrating solvent and isopropyl alcohol) in the same way (application with finger or cotton) to achieve the same results (treatment of topical diseased skin disorders).

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Donna Jagoe whose telephone number is (571) 272-0576. The examiner can normally be reached on Monday through Friday from 8:00 A.M. - 4:30 P.M..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on (571) 272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Donna Jagoe /D. J./
Examiner
Art Unit 1614

September 9, 2009

/Ardin Marschel/
Supervisory Patent Examiner, Art Unit 1614